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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,184

09/24/2004

Alexander D Slowey

57666US005

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32692 7590 10/16/2007
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EXAMINER

GEORGE, KONATA M

ART UNIT

PAPER NUMBER

1616

NOTIFICATION DATE

DELIVERY MODE

10/16/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/509,184

Applicant(s)

SLOWEY ET AL.

Examiner

Konata M. George

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-14 and 17 are pending in this application.

Action Summary

1. The rejection of claims 1-14 and 17 under 35 U.S.C. 112, second paragraph as being indefinite is being maintained for the reasons stated in the office action dated February 26, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-14 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants in the claims recite the phrase "derivatives". Webster's Dictionary defines a derivative as "a substance derived from, or of such composition and properties, that it may be considered as derived from, another substance by chemical change, esp. by the substitution of one or more elements or radicals". Based on this definition it is unclear what the derivative is.

Response to Arguments

3. Applicant's arguments filed July 26, 2007 have been fully considered but they are not persuasive.

Applicant cite in the specification page 4, lines 30-32 to overcome the rejection. This recitation merely describes what the derivative does and not what it is. This rejection is therefore being maintained.

4. The provisional rejection of claims 1, 2, 10, 11, 13 and 14 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending application 10/510,147 is hereby withdrawn in view of applicants arguments.

5. The rejection of claims 1-4 and 17 under 35 U.S.C. 103(a) as being unpatentable over Trofast et al. in view of Ashurst et al. is being maintained for the reasons stated in the office action dated February 26, 2007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1-14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trofast et al. (WO 00/53187) in view of Ashurst et al. (US 6,131,566).

Applicants claim an aerosol composition comprising particles of formoterol, a propellant selected from 1,1,1,2-tetrafluoroethane and 1,2,3,3,3-heptafluoropropane and a bulking agent, contained in a dispenser comprising an aerosol vial that is coated with a fluorocarbon polymer.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Trofast et al. disclose a pharmaceutical combination comprising formoterol and mometasone. Page 3, lines 14-18 teach the composition further containing a one or more pharmaceutically acceptable additives, diluents or carriers. Page 3, lines 22-27 teach that the preferred form of formoterol is the fumarate dihydrate salt and the preferred form of mometasone is the monohydrate of the furoate ester. Page 5, line 24 through page 6, line 11 teach that the composition can be inhaled from a nebulizer, pressured metered dose inhaler, or as a dry powder from a dry powder inhaler. Trofast et al. also teach that a diluent or carrier such as lactose, dextran, mannitol or glucose can be added to the medicament. Trofast et al. also teach that the one or more ingredients are preferably in a micronized dry powder form having a particle size of less than 10 microns. Page 6, lines 13-20 teach that when the system is a pressurized

Art Unit: 1616

inhaler the ingredients are preferably in micronized form and that it is suspended in a liquid propellant such as P134a (tetrafluoro-ethane) and P227 (heptafluoropropane). The propellants can also be used in combination with one or more surfactants or excipients such as ethanol.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Trofast et al. do not teach coating the interior surface of the aerosol vial with a fluorocarbon polymer. It is for this that Ashurst et al. is joined.

Ashurst et al. teach a metered dose inhaler having all or part of its internal surfaces coated with one or more fluorocarbon polymers (abstract). Column 1, lines 50-63 of Ashurst et al. teach that some aerosol drugs tend to adhere to the inner surfaces of inhalers and that coating the interior surfaces can reduce the problem of adhesion or deposition on the can walls.

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Ashurst et al. in the invention of Trofast et al. to teach an aerosol composition comprising particles of formoterol, a propellant and a bulking agent, contained in a dispenser comprising an aerosol vial that is coated with a fluorocarbon polymer. It is the position of the examiner that although the coated

interior surfaces of Ashurst et al. is being used for albuterol, the same holds true for any and all drugs that adhere to the interior walls of aerosol vials. If it is believed, that formoterol adheres to the interior wall of aerosol vials; it would be within reason for one of ordinary skill to apply a substance to the aerosol vials to reduce adhesion.

Response to Arguments

7. Applicant's arguments filed July 26, 2007 have been fully considered but they are not persuasive.

Applicant argues that Trofast et al. do not teach the bulking agent having a submicron particle size. The examiner disagrees. Page 6, lines 9-11 teach that the particle size of the ingredients are preferably less than 10 microns. It is the position of the examiner that any and all particles sizes, including less than 1 micron falls within range taught by Trofast et al.

Conclusion

8. Claims 1-14 and 17 remain rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

Art Unit: 1616

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

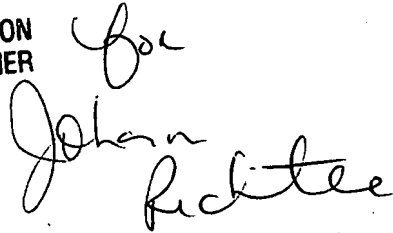
Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Art Unit: 1616

Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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